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GLAXOSMITHKLINE Corporate Intellectual Property - UW2220 P.O. Box 1539 King of Prussia, PA 19406-0939			EXAMINER COLEMAN, BRENDA LIBBY	
			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/074,639	THOMPSON ET AL.
	Examiner Brenda L. Coleman	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- Responsive to communication(s) filed on \_\_\_\_.
- This action is FINAL.  This action is non-final.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_ is/are allowed.
- Claim(s) 1-6 is/are rejected.
- Claim(s) \_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- The specification is objected to by the Examiner.
- The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 The translation of the foreign language provisional application has been received.
- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- Notice of References Cited (PTO-892)
- Notice of Draftsperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/12/2002, 4/18/2002 and 2/3/2002.
- Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- Notice of Informal Patent Application (PTO-152)
- Other: \_\_\_\_

### **DETAILED ACTION**

Claims 1-6 are pending in the application.

#### ***Priority***

1. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/653,815, filed September 1, 2000 and Application No. 09/593,845 filed June 14, 2000. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, **the reference must include the relationship** (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This

time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

### ***Specification***

2. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re*

*Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. The disclosure is objected to because of the following informalities: the specification does not contain a description of the drawings, i.e. Table 1.

Appropriate correction is required.

#### Content of Specification

(g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of the method claims 1-6 are not adequately enabled solely based on cysteine protease provided in the specification. Claims 1-6 are the method of inhibiting any and all diseases and/or disorders associated with cysteine protease, which is not remotely enabled. The scope of claims 1-6 includes diseases

and/or disorders not even known at this time which may be associated with cysteine protease. While treatment of osteoporosis has been linked with cysteine protease, the art does not recognize use of such inhibitors as broad based drugs for treating all disorders instantly embraced.

6. Claims 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) The ring system, benzo[b][1,4]dioxepine is not defined in the specification.

See the species in lines 31-32 on page 142; in lines 3-4 on page 144, in lines 9-10 on page 159; and in lines 13-14 on page 160.

b) The ring system, naphtho[2,1-b]-furan is not defined in the specification.

See the species in lines 11-12 on page 152.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) Claims 1, 3, 5 and 6 are vague and indefinite in that it is not known what is meant by the semi-colon after the first moiety within the definition of R<sup>1</sup>. Semi-colons

Art Unit: 1624

are used to end a definition and commas are used to separate moieties within the definitions.

b) Claims 1, 3, 5 and 6 are vague and indefinite in that it is not known what is meant by the moiety  $R^9(R^{11})NSO_2-$  pyridinyl-phenyl- $CH_2-C(O)$  in the definition of  $R^2$ . It is believed that a comma is needed between the two moieties.

c) Claims 1, 3, 5 and 6 are vague and indefinite in that it is not known what is meant by the moieties pyridinyl-phenyl- $CH_2-C(O)$  and pyridinyl-phenyl- $CH_2-CH_2$  in the definition of  $R^2$ . There is no indication of the point of attachment.

d) Claims 1, 3, 5 and 6 are vague and indefinite in that it is not known what is meant by the moiety pyridinyl-phenyl- $CH_2-CH_2 R^7-N(R^6)-CH(R^8)-Z-$  in the definition of  $R^2$ . It is believed that a comma is needed between the two moieties.

e) Claims 1, 3, 5 and 6 are vague and indefinite in that there are two definitions for the variables  $R^3$  and  $R^4$ .

f) Claims 1, 3, 5 and 6 are vague and indefinite in that it is not known what is meant by the definition of  $R''$  which is selected from the group consisting of..... The moieties should be  $H$ ,  $C_{1-6}$ alkyl,  $Ar-C_{0-6}$ alkyl, and  $Het-C_{0-6}$ alkyl.

g) Claims 1, 3, 5 and 6 are vague and indefinite in that it is not known what is meant by the moiety  $C_{3-6}$ cycloalkyl- $C_{0-6}$ alkyl  $C_{2-6}$ alkenyl in the definition of  $R'''$ . It is believed that a comma is needed between the two moieties.

h) Claims 2 and 4 are vague and indefinite in that it is not known what is meant by "Chemical Name" within the Markush Group of species.

Art Unit: 1624

i) Claims 2 and 4 recite the limitation "5-(2-morpholino-4-yl-ethoxy)-benzofuran" in the species in lines 13-14, 15-16, 17-18, 19-20 and 21-22 on page 139; in lines 5-6, 11-12, 13-14 and 15-16 on page 140; in lines 23-24 on page 142; in lines 15-16 on page 146; in lines 23-24, 25-26, 27-26, 29-30 and 31-32 on page 155; in lines 15-16, 21-22, 23-24 and 25-26 on page 156; in lines 1-2 on page 159; and in lines 25-26 on page 162. There is insufficient antecedent basis for this limitation in the claim.

There is no substitution on the moieties from which it depends.

j) Claims 2 and 4 recite the limitation "5-(2-pyrrolidin-1-yl-ethoxy)-benzofuran" in the species in lines 23-24 on page 139; in lines 1-2 on page 140; and in lines 1-2 and 11-12 on page 156. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

k) Claims 2 and 4 recite the limitation "5-(2-piperidin-1-yl-ethoxy)-benzofuran" in the species in lines 25-26 on page 139; in lines 3-4 on page 140; and in lines 3-4 and 13-14 on page 139. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

l) Claims 2 and 4 are vague and indefinite in that the species in lines 15-16 is a duplicate of the species in lines 13-14 on page 139; and the species in lines 25-26 on page 155 is a duplicate of the species in lines 23-24 on page 155.

m) Claims 2 and 4 are vague and indefinite in that the species in lines 21-22 is a duplicate of the species in lines 19-20 on page 139; and the species in lines 31-32 is a duplicate of the species in lines 29-30 on page 155.

- n) Claims 2 and 4 are vague and indefinite in that the species in lines 1-2 on page 140 is a duplicate of the species in lines 23-24 on page 139; and the species in lines 11-12 is a duplicate of the species in lines 1-2 on page 156.
- o) Claims 2 and 4 are vague and indefinite in that the species in lines 3-4 on page 140 is a duplicate of the species in lines 25-26 on page 139; and the species in lines 13-14 is a duplicate of the species in lines 3-4 on page 156.
- p) Claims 2 and 4 are vague and indefinite in that it is not known what is meant by "buyl" in the species in lines 5-6 on page 140 and the species in lines 15-16 on page 156.
- q) Claims 2 and 4 are vague and indefinite in that the species in lines 17-18 on page 140 is a duplicate of the species in lines 7-8 on page 140; and the species in lines 27-28 is a duplicate of the species in lines 17-18 on page 156.
- r) Claims 2 and 4 are vague and indefinite in that the species in lines 11-16 on page 140 and the species in lines 21-26 on page 156 are triplicates of each other.
- s) Claims 2 and 4 recite the limitation "[...(...benzofuran-5-yloxy)-ethyl]-piperazine-1-carboxylic acid tert-butyl ester" in the species in lines 19-20 on page 140; and in the species in lines 30-31 on page 156. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.
- t) Claims 2 and 4 recite the limitation "5-(2-piperizin-1-yl-ethoxy)-benzofuran" in the species in lines 21-22 on page 140; and the species in lines 31-32 on

page 156. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

u) Claims 2 and 4 are vague and indefinite in that the species in lines 21-26 on page 148 is a duplicate of the species in lines 23-28 on page 140; and the species in line 31 on page 164 through line 4 on page 165 is a duplicate of the species in lines 1-6 on page 157.

v) Claims 2 and 4 are vague and indefinite in that the species in lines 31-32 on page 148 is a duplicate of the species in lines 29-30 on page 140; and the species in lines 9-10 on page 165 is a duplicate of the species in lines 7-8 on page 157.

w) Claims 2 and 4 are vague and indefinite in that the species in lines 27-28 on page 148 is a duplicate of the species in lines 1-2 on page 141; and the species in lines 5-6 on page 165 is a duplicate of the species in lines 11-12 on page 157.

x) Claims 2 and 4 are vague and indefinite in that the species in lines 17-18 on page 143 is a duplicate of the species in lines 9-10 on page 141; and the species in lines 27-28 on page 159 is a duplicate of the species in lines 19-20 on page 157.

y) Claims 2 and 4 are vague and indefinite in that the species in lines 15-16 on page 143 is a duplicate of the species in lines 11-12 on page 141; and the species in lines 25-26 on page 159 is a duplicate of the species in lines 21-22 on page 157.

z) Claims 2 and 4 recite the limitation "5-methoxy-benzofuran" in the species in lines 9-10 on page 141; in lines 17-18 on page 142; in lines 5-6 and 17-18 on page 143; in lines 9-10, 17-18, 25-26 and 31-32 on page 144; in lines 31-32 on page 146; in lines 15-16 and 25-26 on page 147; in lines 5-6 on page 148; in lines 11-12 and 29-30

on page 149; in lines 19-20 on page 150; in lines 1-2 on page 153; in lines 19-20 on page 157; in lines 27-28 on page 158; in lines 15-16 and 27-28 on page 159; in lines 19-20 and 27-28 on page 160; in lines 3-4 and 9-10 on page 161; in lines 9-10 and 25-26 on page 163; in lines 3-4 and 15-16 on page 164; in lines 21-22 on page 165; in lines 7-8 on page 166; in lines 29-30 on page 167; and in lines 11-12 on page 169. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

aa) Claims 2 and 4 recite the limitation "5-bromo-furan" in the species in lines 11-12 on page 141; in lines 5-6 and 11-12 on page 142; in lines 15-16 on page 143; in lines 21-22 on page 157; in lines 15-16 and 21-22 on page 158; and in lines 25-26 on page 159. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ab) Claims 2 and 4 recite the limitation "5-nitro-furan" in the species in lines 13-14 on page 141; and in lines 23-24 on page 157. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ac) Claims 2 and 4 recite the limitation "5-(4-nitro-phenyl)-furan" in the species in lines 15-16 on page 141; and in lines 25-26 on page 157. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ad) Claims 2 and 4 recite the limitation "(4-fluoro-phenoxy)" in the species in lines 17-18 on page 141; and in lines 27-29 on page 157. There is insufficient

antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ae) Claims 2 and 4 recite the limitation "5,6-dimethoxy-benzofuran" in the species in lines 21-22 on page 141; in lines 7-8 and 15-16 on page 142; in lines 31-32 on page 157; and in lines 17-18 and 25-26 on page 158. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

af) Claims 2 and 4 recite the limitation "1-methyl-1H-imidazole" in the species in lines 23-24, 27-28 and 31-32 on page 141; and in lines 1-2, 5-6 and 9-10 on page 158. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ag) Claims 2 and 4 recite the limitation "5-(4-oxy-morpholino-4-yl-ethoxy)-benzofuran" in the species in lines 29-30 on page 141; and in lines 7-8 on page 158. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ah) Claims 2 and 4 recite the limitation "5-hydroxy-benzofuran" in the species in lines 31-32 on page 141; and in lines 9-10 on page 158. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ai) Claims 2 and 4 are vague and indefinite in that the species in lines 1-2 and 9-10 on page 142 and lines 11-12 and 19-20 on page 158 are missing an open "(".

aj) Claims 2 and 4 are vague and indefinite in that the species in lines 9-10 on page 142 is a duplicate of the species in lines 1-2 on page 142; and the species in lines 19-20 on page 158 is a duplicate of the species in lines 11-12 on page 158.

ak) Claims 2 and 4 are vague and indefinite in that the species in lines 13-14 on page 142 is a duplicate of the species in lines 3-4 on page 142; and the species in lines 23-24 on page 158 is a duplicate of the species in lines 13-14 on page 158.

al) Claims 2 and 4 are vague and indefinite in that the species in lines 11-12 on page 142 is a duplicate of the species in lines 5-6 on page 142; and the species in lines 21-22 on page 158 is a duplicate of the species in lines 15-16 on page 158.

am) Claims 2 and 4 are vague and indefinite in that the species in lines 15-16 on page 142 is a duplicate of the species in lines 7-8 on page 142; and the species in lines 25-26 on page 158 is a duplicate of the species in lines 17-18 on page 158.

an) Claims 2 and 4 are vague and indefinite in that the species in lines 5-6 on page 143 is a duplicate of the species in lines 17-18 on page 142; and the species in lines 15-16 on page 159 is a duplicate of the species in lines 27-28 on page 158.

ao) Claims 2 and 4 are vague and indefinite in that the species in lines 7-8 on page 143 is a duplicate of the species in lines 19-20 on page 142; and the species in lines 17-18 on page 159 is a duplicate of the species in lines 29-30 on page 158.

ap) Claims 2 and 4 are vague and indefinite in that the species in lines 15-16 on page 146 is a duplicate of the species in lines 23-24 on page 142; and the species in lines 1-2 on page 159 is a duplicate of the species in lines 25-26 on page 162.

Art Unit: 1624

aq) Claims 2 and 4 are vague and indefinite in that the species in lines 13-14 on page 145 is a duplicate of the species in lines 25-26 on page 142; and the species in lines 23-24 on page 161 is a duplicate of the species in lines 3-4 on page 159.

ar) Claims 2 and 4 are vague and indefinite in that the species in lines 3-4 on page 144 is a duplicate of the species in lines 31-32 on page 142; and the species in lines 13-14 on page 160 is a duplicate of the species in lines 9-10 on page 159.

as) Claims 2 and 4 are vague and indefinite in that it is not known what is meant by "carbamoyl]- -buty}" in the species in lines 23-24 on page 142; in lines 15-16 on page 146; in lines 1-2 on page 159; and in lines 25-26 on page 162.

at) Claims 2 and 4 recite the limitation "3-methyl-benzofuran" in the species in lines 25-26 on page 142; in lines 19-20 on page 143; in lines 27-28 on page 144; in lines 3-4, 9-10 and 13-14 on page 145; in lines 3-4, 19-20 and 29-30 on page 146; in lines 9-10 on page 148; in lines 9-10 on page 149; in lines 21-22 on page 151; in lines 17-18 and 23-24 on page 152; in lines 3-4 and 29-30 on page 159; in lines 5-6, 13-14, 19-20 and 23-24 on page 161; in lines 13-14 and 29-30 on page 163; in lines 7-8 and 19-20 on page 164; in lines 19-20 on page 165; in lines 31-32 on page 167; in lines 27-28 on page 168; and in lines 1-2 on page 169. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

au) Claims 2 and 4 recite the limitation "4,5-dibromo-thiophene" in the species in lines 1-2 on page 143; and in lines 11-12 on page 159. There is insufficient

antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

av) Claims 2 and 4 recite the limitation "(4-chloro-phenyl)-furan" in the species in lines 9-10 on page 143; and in lines 19-20 on page 159. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

aw) Claims 2 and 4 recite the limitation "5-(3-trifluoromethyl-phenyl)-furan" in the species in lines 11-12 on page 143; in lines 21-22 on page 146; in lines 25-26 on page 149; in lines 27-28 on page 150; in lines 21-22 on page 159; in lines 31-32 on page 162; in lines 3-4 on page 166; and in lines 5-6 on page 167. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ax) Claims 2 and 4 recite the limitation "4-fluoro-benzenesulfonyl" in the species in lines 13-14 on page 143; in lines 13-14, 15-16, 17-18 and 19-20 on page 144; in lines 31-32 on page 145; in lines 1-2, 3-4 and 25-26 on page 146; in lines 23-24 on page 159; in lines 23-24, 25-26, 27-28 and 29-30 on page 160; in lines 9-10, 11-12 and 13-14 on page 162; and in lines 3-4 on page 163. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ay) Claims 2 and 4 recite the limitation "2-phenyl-5-trifluoromethyl-oxazole" in the species in lines 23-24 on page 143; in lines 25-26 on page 145; in lines 1-2 on page

160; and in lines 3-4 on page 162. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

az) Claims 2 and 4 are vague and indefinite in that the species in lines 25-26 on page 145 is a duplicate of the species in lines 23-24 on page 143; and the species in lines 3-4 on page 162 is a duplicate of the species in lines 1-2 on page 160.

ba) Claims 2 and 4 recite the limitation "4-methoxy-benzenesulfonyl" in the species in lines 25-26 and 27-28 on page 143; in lines 11-12 on page 144; in lines 29-30 on page 145; in lines 3-4, 5-6 and 21-22 on page 160; and in lines 7-8 on page 162. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bb) Claims 2 and 4 recite the limitation "4-fluoro....benzamide" in the species in lines 1-2 on page 144; and in lines 11-12 on page 160. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bc) Claims 2 and 4 recite the limitation "5-methyl-thiophene" in the species in lines 5-6 on page 144; and in lines 15-16 on page 160. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bd) Claims 2 and 4 recite the limitation "furan-2-carboxylic acid....methyl)-amide" in the species in lines 11-12 on page 144; and in lines 21-22 on page 160. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

Art Unit: 1624

be) Claims 2 and 4 recite the limitation "1-methyl-1H-indole" in the species in lines 15-16 on page 144; in lines 7-8 on page 145; and in lines 1-2 and 15-16 on page 148; in lines 25-26 on page 160; in lines 17-18 on page 163; and in lines 11-12 and 25-26 on page 164. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bf) Claims 2 and 4 are vague and indefinite in that the species in lines 25-26, 27-28 and 29-30 on page 160 is missing a close "J".

bg) Claims 2 and 4 recite the limitation "3-chloro-benzenesulfonyl" in the species in lines 23-24, 25-26 and 27-28 on page 144; and in lines 1-2, 3-4 and 5-6 on page 161. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bh) Claims 2 and 4 recite the limitation "2-fluoro-benzenesulfonyl" in the species in lines 29-30 and 31-32 on page 144; in lines 1-2, 3-4, 5-6 and 7-8 on page 145; and in lines 7-8, 9-10, 11-12, 13-14, 15-16 and 17-18 on page 161. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bi) Claims 2 and 4 recite the limitation "7-methoxy-benzofuran" in the species in lines 1-2 on page 145; in lines 1-2, 17-18 and 27-28 on page 147; in lines 7-8 on page 148; in lines 15-16 on page 149; in lines 11-12 on page 161; in lines 11-12 and 27-28 on page 163; in lines 5-6 and 17-18 on page 164; and in lines 25-26 on page 165. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bj) Claims 2 and 4 are vague and indefinite in that the species in lines 31-32 on page 145 is a duplicate of the species in lines 5-6 on page 145; and the species in lines 9-10 on page 162 is a duplicate of the species in lines 15-16 on page 161.

bk) Claims 2 and 4 recite the limitation "2,2',4-tridueterio" in the species in lines 15-16 on page 145; and in lines 25-26 on page 161. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bl) Claims 2 and 4 recite the limitation "5-methyl-2-phenyl-oxazole" in the species in lines 27-28 on page 145; in lines 17-18 on page 146; and in lines 5-6 and 27-28 on page 162. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bm) Claims 2 and 4 recite the limitation "3,4-dimethoxy....benzamide" in the species in lines 29-30 on page 145; in lines 3-4, 9-10 and 23-24 on page 146; in lines 7-8, 13-14 and 19-20 on page 162; and in lines 1-2 on page 163. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bn) Claims 2 and 4 are vague and indefinite in that the species in lines 3-4 and 11-12 on page 146; and the species in lines 13-14 and 21-22 on page 162 are missing a close "]" and an open "[".

bo) Claims 2 and 4 are vague and indefinite in that the species in lines 5-6 and 7-8 on page 146; and the species in lines 15-16 and 17-18 on page 162 are missing a close "]" and an open "[".

bp) Claims 2 and 4 are vague and indefinite in that the species in lines 9-10 on page 146; and the species in lines 19-20 on page 162 is missing a close "]" and two open "{".

bq) Claims 2 and 4 are vague and indefinite in that the species in lines 23-24 on page 146; and the species in lines 1-2 on page 163 is missing a close "]", a close ")" and an open "{".

br) Claims 2 and 4 recite the limitation "4-methanesulfonyl-benzamide" in the species in lines 11-12 and 25-26 on page 146; in lines 21-22 on page 162; and in lines 3-4 on page 163. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bs) Claims 2 and 4 recite the limitation "2-cyano-benzenesulfonyl" in the species in lines 13-14 and 23-24 on page 146; in lines 23-24 on page 162; and in lines 1-2 on page 163. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bt) Claims 2 and 4 recite the limitation "6-methyl.....nicotinamide" in the species in lines 19-20 on page 146; and in lines 29-30 on page 162. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bu) Claims 2 and 4 are vague and indefinite in that the species in lines 25-26 on page 146; and the species in lines 3-4 on page 163 is missing a close "]", and an open "(".

bv) Claims 2 and 4 are vague and indefinite in that it is not known what is meant by "amnio" in the species in lines 27-28 and 29-30 on page 146; and in lines 5-6 and 7-8 on page 163.

bw) Claims 2 and 4 recite the limitation "(4-methoxy-phenyl)" in the species in lines 27-28 on page 146; and in lines 5-6 on page 163. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bx) Claims 2 and 4 recite the limitation "(3-benzyloxy-4-methoxy-phenyl)" in the species in lines 29-30 on page 146; and in lines 7-8 on page 163. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

by) Claims 2 and 4 recite the limitation "4-chloro-benzenesulfonyl" in the species in lines 13-14, 15-16, 17-18, 19-20 and 21-22 on page 147; and in lines 23-24, 25-26, 27-28, 29-30 and 31-32 on page 163. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

bz) Claims 2 and 4 recite the limitation "3-methoxy-benzenesulfonyl" in the species in lines 23-24, 25-26, 27-28, 29-30 and 31-32 on page 147; in lines 1-2 on page 148; and in lines 1-2, 3-4, 5-6, 7-8, 9-10 and 11-12 on page 164. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

Art Unit: 1624

ca) Claims 2 and 4 recite the limitation "5,6-difluoro-benzofuran" in the species in lines 17-18 and 19-20 on page 148; and in lines 13-14 and 27-28 on page 149; in lines 27-28 and 29-30 on page 164; in lines 23-24 on page 165; and in lines 5-6 on page 166. There is insufficient antecedent basis for this limitation in the claim.

There is no substitution on the moieties from which it depends.

cb) Claims 2 and 4 are vague and indefinite in that the species in lines 19-20 on page 148 is a duplicate of the species in lines 17-18 on page 148; and the species in lines 29-30 on page 164 is a duplicate of the species in lines 27-28 on page 164.

cc) Claims 2 and 4 are vague and indefinite in that the species in lines 17-18 on page 149 is a duplicate of the species in lines 1-2 on page 149; and the species in lines 27-28 on page 165 is a duplicate of the species in lines 11-12 on page 165.

cd) Claims 2 and 4 are vague and indefinite in that the species in lines 29-30 on page 149 is a duplicate of the species in lines 11-12 on page 149; and the species in lines 7-8 on page 166 is a duplicate of the species in lines 21-22 on page 165.

ce) Claims 2 and 4 are vague and indefinite in that the species in lines 23-24 on page 149 is a duplicate of the species in lines 19-20 on page 149; and the species in lines 1-2 on page 166 is a duplicate of the species in lines 31-32 on page 165.

cf) Claims 2 and 4 are vague and indefinite in that the species in lines 1-2 on page 150 is a duplicate of the species in lines 21-22 on page 149; and the species in lines 11-12 on page 166 is a duplicate of the species in lines 31-32 on page 165.

cg) Claims 2 and 4 recite the limitation "6-methyl-pyridine-2-sulfonyl" in the species in lines 1-2, 15-16, 17-18 and 31-32 on page 149; in lines 11-12, 25-26 and 27-

28 on page 165; and in lines 9-10 on page 166. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ch) Claims 2 and 4 recite the limitation "5,6-dimethoxy-benzo[b]thiophene" in the species in lines 1-2 and 17-18 on page 149; and in lines 11-12 and 27-28 on page 165. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ci) Claims 2 and 4 recite the limitation "1-benzyl...pyrrolidine" in the species in lines 3-4 on page 149; and in lines 13-14 on page 165. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

cj) Claims 2 and 4 are vague and indefinite in that the species in lines 3-4 on page 149; and lines 13-14 on page 165 are missing a close ")" and an open "[".

ck) Claims 2 and 4 are vague and indefinite in that the species in lines 5-6 on page 149; and in lines 15-16 on page 165 are missing a close ")" and an open "(".

cl) Claims 2 and 4 recite the limitation "3-methyl-pyridine-2-sulfonyl" in the species in lines 7-8, 9-10, 11-12 and 29-30 on page 149; in lines 17-18, 19-20 and 21-22 on page 165; and in lines 7-8 on page 166. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

cm) Claims 2 and 4 recite the limitation "5-fluoro-benzofuran" in the species in lines 19-20 and 23-24 on page 149; in lines 5-6 and 11-12 on page 151; in lines 29-30

on page 165; in lines 1-2 on page 166; and in lines 15-16 and 21-22 on page 167.

There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

cn) Claims 2 and 4 are vague and indefinite in that the species in lines 3-4 and 5-6 on page 150; and the species in lines 13-14 and 15-16 on page 166 are missing a close ")" and an open "(".

co) Claims 2 and 4 are vague and indefinite in that the species in lines 29-32 on page 150 is a duplicate of the species in lines 3-6 on page 150; and the species in lines 7-10 on page 167 is a duplicate of the species in lines 13-16 on page 166.

cp) Claims 2 and 4 are vague and indefinite in that the species in lines 1-2 on page 151 is a duplicate of the species in lines 7-8 on page 150; and the species in lines 11-12 on page 167 is a duplicate of the species in lines 16-17 on page 166.

co) Claims 2 and 4 are vague and indefinite in that the species in lines 3-4 on page 151 is a duplicate of the species in lines 11-12 on page 150; and the species in lines 13-14 on page 167 is a duplicate of the species in lines 21-22 on page 166

cr) Claims 2 and 4 recite the limitation "2-methyl-furan-3-sulfonyl" in the species in lines 13-14 on page 150; and in lines 23-24 on page 166. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

cs) Claims 2 and 4 recite the limitation "3-fluoro-benzenesulfonyl" in the species in lines 21-22 on page 150; and in lines 31-32 on page 166. There is

Art Unit: 1624

insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

ct) Claims 2 and 4 are vague and indefinite in that it is not known what is meant by "benzensulfonyl" in lines 21-22 on page 150; and in lines 31-32 on page 166.

cu) Claims 2 and 4 are vague and indefinite in that the species in lines 11-16 on page 151 is a duplicate of the species in lines 5-10 on page 151; and the species in lines 21-26 on page 167 is a duplicate of the species in lines 15-20 on page 167.

cv) Claims 2 and 4 are vague and indefinite in that the species in lines 3-8 on page 152 is a duplicate of the species in lines 25-30 on page 151; and the species in lines 13-18 on page 168 is a duplicate of the species in lines 3-8 on page 168.

cw) Claims 2 and 4 are vague and indefinite in that the species in lines 13-14 on page 152 is a duplicate of the species in lines 31-32 on page 151; and the species in lines 23-24 on page 168 is a duplicate of the species in lines 9-10 on page 168.

cx) Claims 2 and 4 recite the limitation "5-fluoro-3-methyl-benzofuran" in the species in lines 7-9 and 13-14 on page 151; and in lines 16-17 and 23-24 on page 167. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

cy) Claims 2 and 4 recite the limitation "6-fluoro-3-methyl-benzofuran" in the species in lines 9-10 and 15-16 on page 151; and in lines 19-20 and 25-26 on pages 167. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

cz) Claims 2 and 4 recite the limitation "3,5-dimethyl-benzofuran" in the species in lines 25-26 on page 151; in lines 3-4 on page 152; and in lines 3-4 and 13-14 on page 168. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

da) Claims 2 and 4 recite the limitation "3-ethyl-benzofuran" in the species in lines 27-28 on page 151; in lines 5-6 on page 152; and in lines 5-6 and 15-16 on page 168. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

db) Claims 2 and 4 recite the limitation "4-methoxy-3-methyl-benzofuran" in the species in lines 29-30 on page 151; in lines 7-8 and 9-10 on page 152; and in lines 7-8, 17-18 and 19-20 on page 168. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

dc) Claims 2 and 4 recite the limitation "6-methoxy-3-methyl-benzofuran" in the species in lines 31-32 on page 151; in lines 13-14 on page 152; and in lines 9-10 and 23-24 on page 168. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

dd) Claims 2 and 4 recite the limitation "5-methoxy-3-methyl-benzofuran" in the species in lines 1-2 on page 152; and in lines 11-12 on page 168. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

Art Unit: 1624

de) Claims 2 and 4 are vague and indefinite in that the species in lines 9-10 on page 152 is a duplicate of the species in lines 7-8 on page 152; and the species in lines 19-20 on page 168 is a duplicate of the species in lines 17-18 on page 168.

df) Claims 2 and 4 recite the limitation "1-methyl-naphtho[2,1-b]-furan" in the species in lines 11-12 on page 152; and in lines 21-22 on page 168. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

dg) Claims 2 and 4 are vague and indefinite in that the species in lines 15-16, 17-18 and 19-20 on page 152; and the species in lines 25-26, 27-28 and 29-30 on page 168. is missing an open "{" and a close "}".

dh) Claims 2 and 4 recite the limitation "2-fluoro-phenylcarbamoyl" in the species in lines 21-22, 23-24, 25-26, 27-28, 29-30 and 31-32 on page 152; in lines 1-2 and 3-4 on page 153; in lines 31-32 on page 168; and in lines 1-2, 3-4, 5-6, 7-8, 9-10 and 11-12 on page 169. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

di) Claims 2 and 4 recite the limitation "4-methyl-2-carboxylic acid....amide" in the species in lines 31-32 on page 152; and in lines 9-10 on page 169. There is insufficient antecedent basis for this limitation in the claim. There is no substitution on the moieties from which it depends.

dj) Claims 2 and 4 recite the limitation "4-methyl-furan" in the species in lines 3-4 on page 153; and in lines 13-14 on page 169. There is insufficient antecedent basis

Art Unit: 1624

for this limitation in the claim. There is no substitution on the moieties from which it depends.

dk) Claims 1-6 are vague and indefinite in that the claim provides for the use of claimed compounds, but the claim does not set forth any steps involved in determining which are the diseases capable of being mediated by inhibiting a cysteine protease. It is unclear which diseases are mediated by inhibiting a cysteine protease. Determining whether a given disease responds or does not respond to such an inhibitor will involve undue experimentation. Suppose that a given drug, which has inhibitor properties in vitro, when administered to a patient with a certain disease, does not produce a favorable response. One cannot conclude that specific disease does not fall within this claim. Keep in mind that:

A. It may be that the next patient will respond. No pharmaceutical has 100% efficacy. What success rate is required to conclude our drug is a treatment? Thus, how many patients need to be treated? If "successful treatment" is what is intended, what criterion is to be used? If one person in 10 responds to a given drug, does that mean that the disease is treatable? One in 100? 1,000? 10,000? Will the standard vary depending on the current therapy for the disease?

B. It may be that the wrong dosage or dosage regimen was employed. Drugs with similar chemical structures can have markedly different pharmacokinetics and metabolic fates. It is quite common for pharmaceuticals to work and or be safe at one dosage, but not at another that is significantly higher or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in

Art Unit: 1624

divided dosages? The optimum route of administration cannot be predicted in advance. Should our drug be given as a bolus iv or in a time release po formulation. Thus, how many dosages and dosage regimens must be tried before one is certain that our drug is not a treatment for this specific disease?

C. It may be that our specific drug, while active in vitro, simply is not potent enough or produces such low concentrations in the blood that it is not an effective treatment of the specific disease. Perhaps a structurally related drug is potent enough or produces high enough blood concentrations to treat the disease in question, so that the first drug really does fall within the claim. Thus, how many different structurally related inhibitors must be tried before one concludes that a specific compound does not fall within the claim?

D. Conversely, if the disease responds to our second drug but not to the first, both of which are inhibitors in vitro, can one really conclude that the disease falls within the claim? It may be that the first compound result is giving the accurate answer, and that the success of second compound arises from some other unknown property, which the second drug is capable. It is common for a drug, particularly in osteoporosis and osteoarthritis, to work by many mechanisms. The history of psychopharmacology is filled with drugs, which were claimed to be a pure receptor XYX agonist or antagonist, but upon further experimentation shown to affect a variety of biological targets. In fact, the development of a drug for a specific disease and the determination of its biological site of action usually precede linking that site of action with the disease. Thus, when mixed results are obtained, how many more drugs need be tested?

E. Suppose that our drug is an effective treatment of the disease of interest, but only when combined with some totally different drug. There are for example, agents in antiviral and anticancer chemotherapy, which are not themselves effective, but are effective treatments when the agents are combined with something else.

Consequently, determining the true scope of the claim will involve extensive and potentially inconclusive research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marquis et al., WO 98/05336. The generic structure of WO 98/05336 encompasses the instantly claimed compounds (see Formula I, page 3) and for the same use as claimed herein. Examples 1-198 differ only in the nature of the R1, A and n substituents. Page 4, line 1 through page 5, line 3 defines the substituent A as C(O) or CH(OH); R1 is R4R'N-C(R3)-Z- and n is 0, 1 or 2. Compounds of the instant invention are generically embraced by WO 98/05336 in view of the interchange ability of the R1, A and n substituents of the azepane ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example n is 2 as well

as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

It is recognized benefit of U.S. Serial Number 09/593,845 filed June 14, 2000 as well as PCT/US99/30730 filed December 12, 1999 and provisional applications 60/113,636 filed December 23, 1998 and 60/164,581 filed November 10, 1999 is being urged. However, the applicant's priority document does not describe the invention of this application serial number 10/074,639. Note for benefit under 35 USC 120 and 35 USC 119, there must be clear support (description and enablement) for claims instantly rejected herein as was set forth in *In re Scheiber* 199 USPQ 782; *In re Lukach*, 169 USPQ 795; *In re Gostelli*, 10 USPQ 2nd 1614; *Kawai v. Metlesics* 178 USPQ 159. Applicants' attention is drawn to the definition of R<sup>1</sup>.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1624

9. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-53 and 62-71 of copending Application No. 10/074,940. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I are embraced by the generic teaching of 10/074,940.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-53 of copending Application No. 09/881,334. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I are embraced by the generic teaching of 09/881,334.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-53 of copending Application No. 10/404,716. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions

Art Unit: 1624

and method of use of the compounds of formula I are embraced by the generic teaching of 10/404,716.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-53 and 62-71 of copending Application No. 10/404,142. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I are embraced by the generic teaching of 10/404,142.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 55-69 and 91-104 of copending Application No. 10/239,343. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I are embraced by the generic teaching of 10/239,343.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1624

14. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of copending Application No. 10/258,053. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I are embraced by the generic teaching of 10/258,053.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/258,412. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I are embraced by the generic teaching of 10/258,412.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-25 and 27-33 of copending Application No. 09/836,586. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I are embraced by the generic teaching of 09/836,586.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1624

17. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-12 of copending Application No. 10/129,669. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I embraces the species of 10/129,669.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-12 of copending Application No. 10/129,668. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I embraces the species of 10/129,668.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-12 of copending Application No. 10/129,322. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I embraces the species of 10/129,322.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-12 of copending Application No. 10/129,678. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I embraces the species of 10/129,678.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-12 of copending Application No. 10/129,680. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I embraces the species of 10/129,680.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-48 and 57-66 of copending Application No. 10/432,425. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I are embraced by the generic teaching of 10/432,425.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 10/035,783. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I are embraced by the generic teaching of 10/035,783.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/478,619. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I are embraced by the generic teaching of 10/478,619.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-12 of U.S. Patent No. 6,534,498. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of formula I embraces the species of U.S. Patent No. 6,534,498.

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 703-305-1880. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

*Brenda Coleman*

Brenda Coleman  
Primary Examiner Art Unit 1624  
December 31, 2003